



2. Upon information and belief, Wockhardt Bio AG is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Grafenauweg 6, 6300 Zug, Switzerland. Upon information and belief, Wockhardt Bio AG is a wholly-owned subsidiary of Wockhardt Limited.

3. Upon information and belief, Wockhardt USA LLC is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 20 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054. Wockhardt USA LLC is the U.S. agent of service for Wockhardt Bio AG. Upon information and belief, Wockhardt USA LLC is a wholly-owned subsidiary of Wockhardt Limited.

4. Upon information and belief, Wockhardt Limited is a corporation organized and existing under the laws of India, having its principal place of business at Wockhardt Towers, Bandra Kurla Complex, Bandra (East), Mumbai, 400051, India.

#### **NATURE OF THE ACTION**

5. This is an action for infringement of U.S. Patent No. 8,017,615 (“the ’615 patent”) and U.S. Patent No. 8,580,796 (“the ’796 patent”), arising under the United States patent laws, Title 35, United States Code, §100 *et seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Wockhardt Bio AG’s filing of an Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal Food, Drug and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to manufacture, use, import, offer to sell and sell certain generic pharmaceutical products (“Wockhardt Bio AG’s generic products”) prior to the expirations of the asserted patents.

#### **JURISDICTION AND VENUE**

6. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has jurisdiction over Wockhardt Bio AG. Wockhardt Bio AG is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Wockhardt Bio AG, directly or through its U.S. agent Wockhardt USA LLC, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Wockhardt Bio AG purposefully has conducted and continues to conduct business, directly or through its U.S. agent Wockhardt USA LLC, in this judicial district, and this judicial district is a likely destination of Wockhardt Bio AG's products. Wockhardt Bio AG has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions in this jurisdiction.

8. This Court has jurisdiction over Wockhardt USA LLC. Upon information and belief, Wockhardt USA LLC has its principal place of business in New Jersey. Wockhardt USA LLC, directly or indirectly, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Wockhardt USA LLC has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions in this jurisdiction.

9. This Court has jurisdiction over Wockhardt Limited. Upon information and belief, Wockhardt Limited, directly or through its subsidiaries Wockhardt Bio AG and Wockhardt USA LLC, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Wockhardt Limited has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions in this jurisdiction.

10. Upon information and belief, Wockhardt Bio AG, Wockhardt USA LLC and Wockhardt Limited operate as a single integrated business. Wockhardt Limited's website, <http://www.wockhardt.com/get-in-touch/international-offices.aspx>, indicates that international offices include Wockhardt Limited (global headquarters), Wockhardt USA LLC and Wockhardt Bio AG. Wockhardt USA LLC's website, [http://www.wockhardttusa.com/about\\_us.html](http://www.wockhardttusa.com/about_us.html), states that "Wockhardt Limited created its US subsidiary Wockhardt USA in early 2004 with a modest portfolio ... Wockhardt USA now represents more than 41% of Wockhardt Ltd's global business."

11. Upon information and belief, this Court additionally has jurisdiction over Wockhardt Limited, Wockhardt Bio AG and Wockhardt USA LLC because they have availed themselves of the rights and benefits of this judicial district, having stated in a purported Offer of Confidential Access, dated February 11, 2014, that "WOCKHARDT LTD., WOCKHARDT USA LLC, AND WOCKHARDT BIO AG (collectively "Wockhardt") hereby extend an offer of confidential access to Abbreviated New Drug Application number 205607 ... This Agreement shall be governed in accordance with the laws of the state of New Jersey."

12. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

#### **FIRST COUNT FOR PATENT INFRINGEMENT**

13. The U.S. Patent and Trademark Office ("PTO") issued the '615 patent on September 13, 2011, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '615 patent is attached as Exhibit A.

14. Otsuka is the owner of the '615 patent by virtue of assignment.



15. The '615 patent expires on June 16, 2024, and pediatric exclusivity relating to the '615 patent expires on December 16, 2024.

16. The '615 patent is directed to and claims, *inter alia*, pharmaceutical solid oral preparations, as well as processes for preparing pharmaceutical solid oral preparations.

17. Otsuka is the holder of New Drug Application ("NDA") No. 21-436 for aripiprazole tablets, which the FDA approved on November 15, 2002. Otsuka lists the '615 patent in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-436.

18. Otsuka markets aripiprazole tablets in the United States under the trademark Abilify<sup>®</sup>.

19. Upon information and belief, Wockhardt Bio AG submitted ANDA No. 20-5607 to the FDA, under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to manufacture, use, import, offer to sell and sell Wockhardt Bio AG's generic products in the United States. Otsuka received a letter from Wockhardt Bio AG dated February 11, 2014 ("Wockhardt Bio AG's 20-5607 letter"), purporting to include a Notice of Certification for ANDA No. 20-5607 under 21 U.S.C. §§ 355(j)(2)(B)(ii) and (iv)(II) and 21 C.F.R. § 314.95(c)(6) as to the '615 patent.

21. Wockhardt Bio AG's 20-5607 letter alleges that "[t]he established name of the proposed drug products that are the subject of Wockhardt's ANDA is Aripiprazole Tablets."

22. Upon information and belief, Wockhardt Bio AG's generic products will, if approved and marketed, infringe at least one claim of the '615 patent.

23. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Wockhardt Bio AG has infringed at least one claim of the '615 patent by submitting, or causing to be submitted to

the FDA, ANDA No. 20-5607 seeking approval to manufacture, use, import, offer to sell and sell Wockhardt Bio AG's generic products before the expiration date of the '615 patent.

24. Upon information and belief, Wockhardt Bio AG's actions relating to Wockhardt Bio AG's ANDA No. 20-5607 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Wockhardt Bio AG, Wockhardt USA LLC and Wockhardt Limited.

### **SECOND COUNT FOR PATENT INFRINGEMENT**

25. The PTO issued the '796 patent on November 12, 2013, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '796 patent is attached as Exhibit B.

26. Otsuka is the owner of the '796 patent by virtue of assignment.

27. The '796 patent expires on September 25, 2022, and pediatric exclusivity relating to the '796 patent expires on March 25, 2023.

28. The '796 patent is directed to and claims, *inter alia*, aripiprazole crystals.

29. Otsuka is the holder of NDA No. 21-436 for aripiprazole tablets, which the FDA approved on November 15, 2002. Otsuka lists the '796 patent in the Orange Book for NDA No. 21-436.

30. Otsuka markets various dosage forms of aripiprazole tablets in the United States under the trademark Abilify<sup>®</sup>.

31. Upon information and belief, Wockhardt Bio AG submitted ANDA No. 20-5607 to the FDA, under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to manufacture, use, import, offer to sell and sell Wockhardt Bio AG's generic products in the United States.

32. Wockhardt Bio AG's 20-5607 letter purports to include a Notice of Certification for ANDA No. 20-5607 under 21 U.S.C. §§ 355(j)(2)(B)(ii) and (iv)(II) and 21 C.F.R. § 314.95(c)(6) as to the '796 patent.

33. Upon information and belief, Wockhardt Bio AG's generic products will, if approved and marketed, infringe at least one claim of the '796 patent.

34. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Wockhardt Bio AG has infringed at least one claim of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-5607 seeking approval to manufacture, use, import, offer to sell and sell Wockhardt Bio AG's generic products before the expiration date of the '796 patent.

35. Upon information and belief, Wockhardt Bio AG's actions relating to Wockhardt Bio AG's ANDA No. 20-5607 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Wockhardt Bio AG, Wockhardt USA LLC and Wockhardt Limited.

36. **WHEREFORE**, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants Wockhardt Bio AG, Wockhardt USA LLC and Wockhardt Limited on the patent infringement claims set forth above and respectfully requests that this Court:

- 1) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Wockhardt has infringed at least one claim of the '615 patent through Wockhardt Bio AG's submission of ANDA No. 20-5607 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Wockhardt Bio AG's generic products in the United States before the expiration of the '615 patent;

- 2) order that the effective date of any approval by the FDA of Wockhardt Bio AG's generic products be a date that is not earlier than the expiration of the '615 patent, or such later date as the Court may determine;
- 3) enjoin Wockhardt from the manufacture, use, import, offer for sale and sale of Wockhardt Bio AG's generic products until the expiration of the '615 patent, or such later date as the Court may determine;
- 4) enjoin Wockhardt and all persons acting in concert with Wockhardt, from seeking, obtaining or maintaining approval of Wockhardt Bio AG's ANDA No. 20-5607 until the expiration of the '615 patent;
- 5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Wockhardt has infringed at least one claim of the '796 patent through Wockhardt Bio AG's submission of ANDA No. 20-5607 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Wockhardt Bio AG's generic products in the United States before the expiration of the '796 patent;
- 6) order that the effective date of any approval by the FDA of Wockhardt Bio AG's generic products be a date that is not earlier than the expiration of the '796 patent, or such later date as the Court may determine;
- 7) enjoin Wockhardt from the manufacture, use, import, offer for sale and sale of Wockhardt Bio AG's generic products until the expiration of the '796 patent, or such later date as the Court may determine;
- 8) enjoin Wockhardt and all persons acting in concert with Wockhardt, from seeking, obtaining or maintaining approval of Wockhardt Bio AG's ANDA No. 20-5607 until the expiration of the '796 patent;



- 9) declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Otsuka costs, expenses and disbursements in this action, including reasonable attorney fees; and
- 10) award Otsuka such further and additional relief as this Court deems just and proper.

Respectfully submitted,

s/ John F. Brenner

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